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HEALTH ADVISORY FOR PERFLUOROOCTANESULFONIC ACID (PFOS) CHEMICAL ABSTRACT SERVICES REGISTRY NUMBER (CASRN) 1763-23-1

Prepared by:
Office of Toxicity Assessment
Illinois Environmental Protection Agency
April 16, 2021

REASON FOR ACTION

As a result of a Per- and Polyfluoroalkyl Substances (PFAS) sampling initiative of community water supplies (CWS) undertaken by the Illinois Environmental Protection Agency (Illinois EPA), Perfluorooctanesulfonic Acid (PFOS) has been confirmed in a well at a CWS. In accordance with 35 Illinois Administrative Code 620.605(a), the Illinois EPA is issuing a health advisory for Perfluorooctanesulfonic Acid. Section 620.605(a) directs the Illinois EPA to issue a health advisory for a chemical substance if all of the following conditions are met:

1) A community water supply well is sampled, and a substance is detected and confirmed by resampling;

2) There is no standard under Section 620.410 for such chemical substance; and

3) The chemical substance is toxic or harmful to human health according to the procedures of Appendix A, B, or C.

The health advisory guidance level for PFOS is 0.000014 milligrams per liter (mg/L), or 14 nanograms per liter (ng/L) or parts per trillion (ppt).

The health advisory will be published in the Environmental Register (publication of the Illinois Pollution Control Board), and placed at the website: https://pcb.illinois.gov/Resources/News

The health advisory will also be placed on Illinois EPA's website at: https://www2.illinois.gov/epa/topics/water-quality/pfas/Pages/pfas-healthadvisory.aspx

PURPOSE OF A HEALTH ADVISORY

In accordance with 35 Ill. Adm. Code 620.601, the purpose of a health advisory is to provide guidance levels that, in the absence of an applicable groundwater quality standard under Section 620.410, must be considered by Illinois EPA in: 1) establishing groundwater cleanup or action levels whenever there is a release or substantial threat of a release of a hazardous substance, pesticide, or another contaminant that represents a significant hazard to public health or the environment; 2) determining whether a community water supply is taking its raw water from a site or source consistent with regulatory requirements; and 3) developing Illinois Pollution Control Board (Board) rulemaking proposals for new or revised numerical standards.

Health advisories serve as informal technical guidance, intended to provide information about contaminant exposures and potential public health impacts. The guidance level represents concentrations in drinking water at which no adverse health effects are expected to occur. Guidance levels are not enforceable or intended to be used as drinking water standards, also known as maximum contaminant levels (MCLs).

HEALTH ADVISORY GUIDANCE LEVEL FOR PFOS

Through issuance of this Health Advisory, Illinois EPA is providing public notice of its guidance level for PFOS in drinking water. For non-carcinogenic health effects, the guidance level is 0.000014 milligrams per liter (mg/L), or 14 nanograms per liter (ng/L) or parts per trillion (ppt).

Section 620.605 prescribes the methods for developing health advisories for carcinogens and non-carcinogens. PFOS does not meet the definition of a carcinogen, as defined at Section 620.110; therefore, the method for developing a health advisory for non-carcinogens was used. Briefly, this method specifies that the United States Environmental Protection Agency (U.S. EPA) MCL or maximum contaminant level goal (MCLG) is the guidance level, if available, or the human threshold toxicant advisory concentration (HTTAC) must be determined using the procedures contained in Appendix A of Section 620. U.S. EPA has not published an MCL or MCLG for PFOS; therefore, Illinois EPA used the Appendix A procedures to calculate a HTTAC for PFOS.

Appendix A specifies, in prescribed order, the toxicological data to be used in developing guidance levels. To determine appropriate toxicological data in accordance with nationally accepted guidelines, pursuant to the Illinois Groundwater Protection Act (415 ILCS 55-8(a)), Illinois EPA relied upon U.S. EPA guidance titled, *"Tier 3 Toxicity Value White Paper"* (paper), dated May 16, 2013, prepared by the U.S. EPA Office of Solid Waste and Emergency Response (OSWER) Human Health Regional Risk Assessors Forum. The paper lists a hierarchy of sources to be used when determining an appropriate toxicological value for use in human health assessments. The hierarchy for selection of toxicity values is as follows:

Tier 1: U.S. EPA Integrated Risk Information System (IRIS).

Tier 2: U.S. EPA Provisional Peer-Reviewed Toxicity Values (PPRTVs).

Tier 3: In the order in which they are presented:

1) United States Health and Human Services Agency for Toxic Substances and Disease Registry (ATSDR) Dose Minimal Risk Levels (dose MRLs).

2) California EPA, Office of Environmental Health Hazard Assessment (OEHHA).

3) PPRTV "Appendix" Values.

4) Health Effects Assessment Summary Table (HEAST).

ATSDR published a peer reviewed toxicological (tox) profile titled, "*Toxicological Profile for Perfluoroalkyls"* (tox profile), for four PFAS, including PFOS, in the Federal register on July 19, 2018 for a 60-day public comment period. The comment period closed on September 17, 2018. The toxicity values in the tox profile are considered "draft" until they have been finalized following the public comment period. Following the close of the comment period, ATSDR submitted their toxicological profile to the Office of Management and Budget in December 2019. In November 2018, ATSDR published drinking water MRLs using the recommended dose MRLs included within the tox profile.

ATSDR's tox profile recommends an intermediate dose MRL equal to 0.000002 (2E-06) mg/kg-day. The value is based on a two-generation study by Luebker et al., titled, "*Two-Generation Reproduction and Cross-Foster Studies of Perfluorooctanesulfonate (PFOS) in Rats*", published in 2005. ATSDR lists the critical effects as delayed eye opening and decreased pup body weight in rats. The Wambaugh pharmacokinetic (PK) model was used to derive an time-weighted average (TWA) serum concentration from a no observed adverse effects level (NOAEL) of 0.1 mg/kg-day in rats. The TWA serum concentration was then used to calculate a human equivalency dose (HED) of 0.000515 in units of milligram per kilogram per day (mg/kg-day).

A total uncertainty factor (UF) of 30 (UF of 10 to account for intrahuman variability and UF of 3 to account for toxicodynamic differences between animals and humans) was applied to the HED. In addition to the total UF of 30, ATSDR applied a modifying factor (MF) of 10 for a concern that immunotoxicity, or decreased vaccine response, may be a more sensitive endpoint. ATSDR reviewed four mouse studies associated with suppressed or decreased immune response. However, the lack of human dosing data and lack of low-dose confirmation of effects in animals for short term studies precluded the use of immunotoxicity data in developing an oral reference dose (RfD). For the critical effect of immunotoxicity, the studies provided NOAELs ranging from 0.0167 mg/kg-day to 0.00016 mg/kg-day, and LOAELs (lowest observed adverse effect levels) ranging from 0.083 mg/kg-day to 0.00166 mg/kg-day, below the NOAEL of 0.1 mg/kg-day used to calculate the HED. The immunotoxicity studies were conducted on two mouse species lacking PK model parameters; therefore, a serum concentration for calculating a HED cannot be determined for immunotoxicity from the studies. ATSDR applied a total UF/MF of 300 in the calculation of its dose MRL.

$$dose\ MRL = \frac{HED}{UF/MF}$$

$$dose\ MRL = \frac{0.000515\ mg/kg\text{-}day}{300}$$

$$dose\ MRL = 0.0000017\ mg/kg\text{-}day$$

Rounded to one significant digit:

$$dose\ MRL = 0.000002\ mg/kg\text{-}day$$

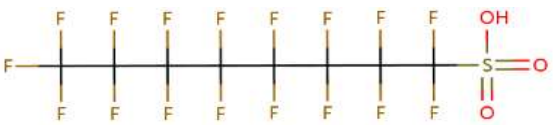
A UF of 1 may be used to extrapolate a chronic value from an intermediate (subchronic) value when developing a HED using a TWA serum concentration. Using the ATSDR dose MRL of 0.000002 (2E-06) mg/kg-day and the procedures outlined in Section 620.Appendix A, the calculated HTTAC for drinking water is 0.000014 mg/L, or 14 ng/L or ppt for non-carcinogen effects.

CHEMICAL CHARACTERISTICS AND POTENTIAL ADVERSE HEALTH EFFECTS

General Description of PFOS

Perfluorooctanesulfonic Acid (CASRN 1763-23-1), also known as heptadecafluorooctane-1-sulfonic acid, or PFOS, is a synthetic chemical which is part of a larger class of chemicals referred to as per- and polyfluoroalkyl substances. PFAS have been manufactured since the middle 20th Century, and are known for their chemical and physical properties that impart oil and water repellency, temperature resistance, and friction reduction to a wide range of products, including, but not limited to, textile coatings, paper products, food wrappers, cosmetic and personal care products, non-stick cookware and fire-fighting foams. PFAS are also used in the semiconductor, aerospace, oil production and mining, and metal plating industries, to name a few. PFAS enter the environment through industrial manufacturing, and the use and disposal of PFAS-containing products. The chemical and physical properties of PFOS make it mobile, persistent and bioaccumulative, meaning fish and other animals may accumulate PFOS in animal tissue when their food sources are contaminated with PFOS. PFOS is not known to degrade in the environment.

Structural Identifier



Chemical Identifier

$C_8F_{17}SO_3H$

Potential Adverse Health Effects of PFOS

Limited epidemiology studies on humans suggest associations between PFOS exposure and several possible health outcomes:

- Pregnancy-induced hypertension/pre-eclampsia
- Liver damage
- Increased serum lipids, primarily total cholesterol and LDL cholesterol
- Increased thyroid disease
- Decreased antibody response to vaccines
- Decreased fertility
- Decreased birth weight
- Osteoarthritis in women under 50 years of age

Most information regarding health effects of PFOS is derived from animal studies, primarily via the ingestion, or oral exposure, route. Laboratory studies observed the following effects in animals exposed to PFOS:

- Liver damage
- Neurodevelopmental effects
- Suppressed immune response
- Skeletal malformations
- Decreased weight of offspring

Carcinogenic Potential

Section 620.110, defines a carcinogen as a contaminant that is classified as: 1) a Category A1 or A2 Carcinogen by the American Conference of Governmental Industrial Hygienists (ACGIH); 2) a Category 1 or 2A/2B Carcinogen by the World Health Organization's International Agency for Research on Cancer (IARC); 3) a "Human Carcinogen" or "Anticipated Human Carcinogen" by the United States Department of Health and Human Service National Toxicological Program (NTP); or 4) a Category A or B1/B2 Carcinogen by the U.S. EPA in IRIS or a Final Rule issued in a Federal Register notice by the U.S. EPA. PFOS does not meet the definition of a carcinogen; however, there is suggestive evidence of increased risk for kidney and testicular cancers in highly exposed humans.

ATTACHMENT TO HEALTH ADVISORY
FOR
PERFLUOROOCTANESULFONIC ACID (PFOS)
CASRN 1763-23-1

OVERVIEW OF KEY STUDIES

For information regarding the studies used by ATSDR for derivation of its PFOS dose MRL, refer to the draft Toxicological Profile for Perfluoroalkyls, located at: https://www.atsdr.cdc.gov/toxprofiles/tp.asp?id=1117&tid=237

DERIVATION OF THE HEALTH ADVISORY FOR PFOS

The first step in the derivation of a health advisory is to determine whether the chemical substance presents a carcinogenic risk to humans. PFOS does not meet the definition of a carcinogen as specified in Section 620. Therefore, the guidance level is based on non-carcinogenic effects of this chemical.

In deriving a guidance level to protect against a health effect for which there is a threshold dose below which no damage occurs (i.e., non-carcinogen effects), Section 620.605 specifies that U.S. EPA's MCLG, if available, is the guidance level. U.S. EPA has not published a MCLG for PFOS; therefore, Illinois EPA must calculate the HTTAC as the guidance level, using the procedures specified in Appendix A of Section 620.

Appendix A specifies in subsection (a) that the HTTAC is calculated as follows:

$$HTTAC = \frac{RSC \bullet ADE}{W}$$

Where:

HTTAC = Human threshold toxicant advisory concentration in milligrams per liter (mg/L).

RSC = Relative source contribution, the relative contribution of the amount of exposure to a chemical via ingestion of drinking water when compared to total exposure to that chemical from all sources. Valid chemical-specific data shall be used if available. If valid chemical-specific data are not available, a value of 20% (= 0.20) must be used.

ADE = Acceptable daily exposure of a chemical in milligrams per day (mg/d) as determined in accordance with Appendix A, subsection (b).

W = Per capita daily water consumption equal to 2 liters per day (L/d).

Subsection (b) of Appendix A specifies that the ADE be calculated using, in specified order: a U.S. EPA verified RfD (an estimate of a daily exposure to a chemical which is expected to be without adverse health effects for humans for a lifetime of exposure in units of mg/kg-day); a NOAEL which has been identified as a result of human exposures; a LOAEL which has been identified as a result of human exposures; a NOAEL which has been determined from studies with laboratory animal; and a LOAEL which has been determined from studies with laboratory animals.

Illinois EPA selected the ATSDR recommended dose MRL of 0.000002 (2E-06) mg/kg-day as the verified RfD for use in calculating the ADE. The ADE equals the product of multiplying the toxicity value by 70 kilograms (kg), which is the assumed average body weight of an adult human per Section 620:

$$ADE = 0.000002\,mg/kg\text{-}day \bullet 70\,kg = 0.00014\,mg/day$$

The next step in the development of the HTTAC is the evaluation of chemical-specific RSC data available for the chemical. Illinois EPA evaluated data from ATSDR, U.S. EPA Office of Water, and values developed by other states. There is little scientific consensus regarding the contribution of drinking water to the total amount of PFAS exposure to humans. Humans are exposed to PFOS through a variety of media, including, but not limited to air emissions, ingestion of fish or other animals exposed to PFOS, dermal exposure and incidental exposure from PFOS-containing consumer products, and bioaccumulation in edible plants, much of which varies on a site-specific basis. Due to this lack of consensus, Illinois EPA elected to use the conservative default value of 20% (0.20) for its HTTAC calculation.

Finally, the HTTAC is calculated by the product of the RSC and the ADE, divided by the per capita daily water ingestion rate, specified in Appendix A as equal to 2 L/day:

$$HTTAC\ (mg/L) = \frac{0.20 \bullet 0.00014\,mg/day}{2\,L/day}$$

$$HTTAC\ (mg/L) = \frac{0.000028\,mg/day}{2\,L/day}$$

$$HTTAC = 0.000014\ mg/L$$

or:

14 ng/L or ppt

The final step in ensuring a calculated guidance level is appropriate is to compare the guidance level to the chemical's practical quantitation limit (PQL), or minimum reporting level (MRL). U.S. EPA's Method 537.1 for analyses of PFAS drinking water samples states the PFOS MRL is 2 ng/L, which is below the calculated guidance level of 14 ng/L. Therefore, the guidance level is appropriate.

REFERENCES

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